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FEB 20 2007

**Amendment and Response**

Serial No.: 10/810,956

Confirmation No.: 9825

Filed: March 26, 2004

For: THERMAL SURGICAL PROCEDURES AND COMPOSITIONS

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**Remarks**

The Office Action mailed November 17, 2006, has been received and reviewed. Claims 2 and 3 have been amended, claims 7-31 have been canceled, and new claims 32-52 have been presented. As a result, claims 1-6 and 32-52 are pending in the present application.

**Claims 2 & 3**

Claims 2 and 3 have been amended to correct a typographical error discovered during preparation of this response.

**New Claims 32-52**

Applicants are presenting new claims 32-52 to provide more comprehensive coverage of Applicants' invention. Further, Applicants submit that new claims 32-52 are patentable over the cited art and respectfully request that these claims be entered and considered by the Examiner.

Support for new claims 32-52 may be found in the specification and claims as filed, for example, original claims 2-6 and 8-12, as well as at page 13, line 27, page 15, lines 22-27 and page 27, lines 16-18 of the specification.

**The 35 U.S.C. §102 Rejection**

Claims 1 and 3-6 were rejected under 35 U.S.C. §102(b) as being anticipated by Edwards et al. (U.S. Patent No. 5,472,441). Applicants respectfully traverse this rejection.

"[F]or anticipation under 35 U.S.C. §102, the reference must teach *every aspect* of the claimed invention, either explicitly or impliedly." M.P.E.P. §706.02 (emphasis added). Applicants respectfully assert that claims 1 and 3-6 are not anticipated by Edwards et al. because this document fails to teach, either explicitly or impliedly, each and every aspect of claims 1 and 3-6.

Edwards et al. teach methods for "treating body tissues containing cancerous cells or non-malignant tumors with RF ablation, alone or in combination with systemic or localized chemotherapy" (Edwards et al., abstract). The methods include use of devices including

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electrodes with a hollow core, a closed sharpened distal tip, and a plurality of fluid distribution ports for distribution of fluid treatment agents into the tissue (Edwards et al., abstract). The fluid can be saline or a chemotherapeutic fluid such as liquid containing a cytotoxic agent or a cytotoxic gas (Edwards et al., abstract and col. 3, lines 18-19).

Independent claim 1 recites a method of performing a thermal surgical procedure including contacting identified biological material with an inflammation-inducing composition, wherein inflammation is induced in at least a portion of the identified biological material.

It is asserted in the Office Action that Edwards et al. teach "contacting the biological material with an inflammation inducing composition, wherein inflammation is induced in at least a portion of the identified biological material," with support for the assertion based on citations to the abstract; column 9, lines 16-24; and column 11, lines 7-9 and 43-44 of Edwards et al. (page 2, last paragraph of the Office Action mailed November 17, 2006).

Applicants submit, however, that Edwards et al. do not, in fact, teach contacting biological material with an inflammation inducing composition. Nor do Edwards et al. teach inducing inflammation in at least a portion of the biological material.

Column 9, lines 16-24 of Edwards et al. discloses that, in one embodiment, "the fluid introduction precedes or is concurrent with the application of RF energy, whereby the heating facilitates and increases the penetration of the tissue by the chemotherapeutic fluid." Column 11, lines 7-9 and 43-44 of Edwards et al. disclose that "chemotherapeutic agents suitable for use in the method of this invention include, but are not limited to antineoplastic agents" (lines 7-9) and that these chemotherapeutic agents may include "Interferon- $\alpha$ , Interferon- $\beta$ , Interferon- $\gamma$ , Interleukin-2, Lentinan, Lonidamine, Mitoguanzone, [and] Mitoxantrone" (lines 43-44).

Edwards et al. do not, however, teach that the chemotherapeutic fluid contacting the tissue is "an inflammation inducing composition" -- nor do Edwards et al. teach contacting identified biological material with the inflammation inducing composition "wherein inflammation is induced in at least a portion of the identified biological material" (as recited in claim 1). As a result, no explicit evidence has been identified in either Edwards et al., or in the general

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knowledge of the skilled artisan, showing that the fluids taught in the disclosure of Edwards et al. are inflammation inducing compositions.

Thus, it appears that the rejection of claims 1 and 3-6 as anticipated by Edwards et al. is based on a theory of "inherency," i.e., that the disclosure of Edwards et al. inherently meets the limitations of claims 1 and 3-6. Applicants assert, however, that the burden for establishing that Edwards et al. inherently teach these aspects of claims 1 and 3-6 has not been met.

"The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic." MPEP §2112(IV) (page 2100-47, 8<sup>th</sup> Ed., Rev. 5 (August 2006), emphasis in original, *citing, In re Rijckaert*, 9 F.3d, 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993)). "In relying upon the theory of inherency the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." MPEP §2112(IV) (page 2100-48, 8<sup>th</sup> Ed., Rev. 5 (August 2006), *citing, Ex parte Levy*, 17 USPQ2d 1461, 1464 (B. Pat. App. & Inter. 1990) (emphasis in original).

There is, however, no discussion in this anticipation rejection (provided at pages 2 to 3 of the Office Action mailed November 17, 2007) substantiating that the fluids disclosed in Edwards et al. necessarily induce inflammation in identified biological material. Although it is asserted that Edwards et al. teach "contacting the biological material with an inflammation inducing composition," the cited passages of Edwards et al. do not teach that the disclosed materials necessarily induce inflammation. Thus, Applicants respectfully assert that the requirements for anticipation based on inherency have not been met with respect to claims 1 and 3-6.

Furthermore, Applicants respectfully point out that there is no explicit or implicit teaching in Edwards et al. of methods for inducing inflammation in at least a portion of identified biological material. Edwards et al. teach that "[a]pplication of saline fluid can reduce dessication of tissue adjacent the electrode surfaces" (Edwards et al., col. 10, lines 55-56), that "[a]pplication of chemotherapeutic substances before application of the ablation energy can exploit the effects of the *[sic]* heating the tissue and the fluid to increase distribution of the fluid in the adjacent tissues" (Edwards et al., col. 10, lines 57-60), and that "[a]pplication of chemotherapeutic

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substances after ablation forming an encapsulated lesion can reduce distribution of the chemotherapeutic agent to tissue beyond the ablation capsule, concentrating its activity to the tissues within the capsule and reducing and almost eliminating the systemic effects of the treatment" (Edwards et al., col. 10, lines 60-65). None of these disclosed outcomes of applying saline or chemotherapeutic agents to tissues in conjunction with the ablation methods taught by Edwards et al. teach, either explicitly or implicitly, that inflammation is induced thereby.

For at least the foregoing reasons, Applicants submit that claims 1 and 3-6 are not anticipated by Edwards et al. Reconsideration and withdrawal of the rejection are, therefore, respectfully requested.

**The 35 U.S.C. §103 Rejection**

Claims 1 and 2 were rejected under 35 U.S.C. §103(a) as being unpatentable over Daniel et al. (U.S. Publication 2002/0133148 A1) in view of Edwards et al. (U.S. Patent No. 5,472,441). Applicants respectfully traverse this rejection.

In order to establish a *prima facie* case of obviousness, the Examiner must establish that there is a motivation to combine the documents (or modify the teachings of a document) to achieve the claimed invention, with a reasonable expectation of success. Further, the references must teach or suggest every element of the claimed invention. For at least the reasons set forth below, it is respectfully submitted that the Examiner has failed to make the requisite showing of a *prima facie* case of obviousness.

Applicants agree with the Examiner that Daniel et al. fail to teach contacting selected biological material with compositions that induce inflammation in at least a portion of the identified biological material. Applicants, however, also submit that the proposed combination of Daniel et al. and Edwards et al. does not teach every aspect of claims 1 & 2.

As discussed above with respect to the anticipation rejection of claims 1 and 3-6, Edwards et al. do not teach contacting the biological material with an inflammation inducing composition, wherein inflammation is induced in at least a portion of the identified biological material. Nor does Edwards et al. suggest such a method. Furthermore, Daniel et al. does not address this

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shortcoming of Edwards et al. Thus, the proposed combination of Daniel et al. and Edwards et al. fails to teach or suggest each and every aspect of claims 1 & 2 as is required for a *prima facie* case of obviousness.

For at least the foregoing reasons, Applicants respectfully submit that a *prima facie* case of obviousness has not been established with respect to claims 1 & 2. Reconsideration and withdrawal of the rejection of claims 1 and 2 are, therefore, respectfully requested.

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Summary

It is respectfully submitted that claims 1-6 and 32-52 are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representatives, at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted

By

Mueeting, Raasch &amp; Gebhardt, P.A.

P.O. Box 581415

Minneapolis, MN 55458-1415

Phone: (612) 305-1220

Facsimile: (612) 305-1228

Customer Number 26813

20 FEB. 2007

Date

By: 

Kevin W. Raasch

Reg. No. 35,651

Direct Dial (612) 305-1218

CERTIFICATE UNDER 37 CFR §1.8:

The undersigned hereby certifies that the Transmittal Letter and the paper(s), as described hereinabove, are being transmitted by facsimile in accordance with 37 CFR §1.6(d) to the Patent and Trademark Office, addressed to Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 20 day of February, 2007, at 12:45 pm (Central Time).

By: Name: Sandra J. Truehart